

Claims

1. A process for the preparation of crystalline Carvedilol Form-II using novel salts of Carvedilol comprising steps:

- 5 • Reaction of 4-(2,3-epoxy propoxy) carbazole with 2-(2-methoxy phenoxy) ethyl amine in the molar ratio of 1:2.0 to 1:2.5 in organic solvents selected from monochlorobenzene, ethylene glycol, dimethyl ether (monoglyme) or their mixtures thereof.
- 10 • Adjustment of pH after completion of the reaction with organic acid(s) in presence of water, organic solvent(s) and isolation of novel Carvedilol salts.
- Treating the salts with base(s) in presence of water and methylene chloride followed by separation of the organic & aqueous layers.
- Drying of organic layer followed by removal of solvent and crystallization of the residue in ethyl acetate.

15

2. A process as claimed in claim 1, wherein the organic acid(s) is selected from oxalic acid and salicylic acid.

20 3. A process as claimed in claim 1, wherein the pH is adjusted to 2.0 to about 3.0 and preferably between 2.5 to about 2.8.

4. A process as claimed in claim 1, wherein the organic solvent(s) used during pH adjustment is selected from isopropyl acetate, chlorobenzene or mixtures thereof.

25 5. A process as claimed in claim 1, wherein the base(s) are selected from alkali, alkaline metal hydroxides, ammonia, organic bases such as triethyl amine, methylamine.

30 6. A process as claimed in claims 1 & 5 wherein the preferred base is aq.ammonia.

30

10

7. A process as claimed in claim 1, wherein the novel carvedilol salts are carvedilol oxalate and carvedilol salicylate.
8. A process for the preparation of carvedilol oxalate and carvedilol salicylate comprising
 - 5 • Reaction of 4-(2,3-epoxy propoxy) carbazole with 2-(2-methoxy phenoxy) ethyl amine in the molar ratio of 1:2.0 to 1:2.5 in presence of suitable organic solvent(s).
 - Adjustment of pH after completion of the reaction with organic acid(s) in presence of water, organic solvent(s) and isolation of novel Carvedilol salts.
- 10 9. A process as claimed in claim 8, wherein the organic acid(s) is selected from oxalic acid and salicylic acid.
10. A process as claimed in claim 8, wherein the pH is adjusted to 2.0 to about 3.0 and preferably between 2.5 to about 2.8.
- 15 11. A process as claimed in claim 8, wherein the organic solvent(s) used during pH adjustment is selected from isopropyl acetate, chlorobenzene or mixtures thereof.

20

25

30